THE EFFECTIVENESS OF BENZYDAMINE HYDROCHLORIDE GARGLE VERSUS THROAT SPRAY IN PAIN CONTROL POST TONSILLECTOMY PATIENT:

A RANDOMIZED CONTROLLED TRIAL

BY

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Thank you Allah S.W.T to give me a strength to complete my thesis on time.

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ABSTRAK (BAHASA MELAYU)

Pengenalan : Kesakitan selepas pembedahan tonsil adalah komplikasi yang tidak diingini di mana ianya boleh mengganggu emosi dan aktiviti harian pesakit. Terdapat banyak kajian yang dijalankan untuk membantu pesakit mengurangkan tahap kesakitan selepas pembedahan tonsil. Antaranya, beberapa teknik pembedahandan ubat-ubatan yang berbeza telah diperkenalkan untuk mencari rawatan yang terbaik untuk mengurangkan kesakitan selepas pembedahan tonsil. Dalam kajian ini, kami memberi tumpuan lebih kepada ubat tahan sakitsetempat dengan kaedah penggunaan yang berbeza.

Objektif :Untuk membandingkan keberkesanan ubat tahan sakit setempat yang mengandungi Benzydamine Hydrochloride dengan kaedahpenggunaan yang berbeza iaitu berkumur berbanding semburan tekak dalam mengawal kesakitan selepas pembedahan tonsil.

Kaedah:

Seramai 92 pesakit yang berumur di antara 13 hingga 40 tahun yang menjalani pembedahan tonsilbersama atau tanpa pembedahan adenoid telah terlibat di dalam kajian ini. Mereka telah dibahagikan secara rawak kepada dua kumpulan dengan empat puluh enam pesakit dalam setiap kumpulan dilabel sebagai kumpulan berkumur dan kumpulan semburan. Tahap kesakitan bagi kedua-dua kumpulan dinilai dengan menggunakan Visual Analogue Score (VAS) sekurang-kurangnya 6 jam selepas pembedahan sebagai penanda aras tahap kesakitan diikuti hari pertama, keempat dan ketujuh selepas pembedahan.

Keputusan: Dalam analisis antara perbezaan kumpulan berkumur dan semburan tekak, ia menunjukkan perbezaan tahap kesakitan (menggunakan skala VAS) yang signifikan ($p < 0.001$)

Kesimpulan: Menggunakan semburan tekak sebagai kaedah untuk menyampaikan ubat tahan sakit setempat lebih memberikan manfaat dalam mengawal kesakitan untuk pesakit selepas pembedahan tonsil

ABSTRACT (ENGLISH)

Introduction: Post tonsillectomy pain is an undesirable complication for the patient which can disturb patient emotion and daily activity. There are many studies conducted to improve pain in post tonsillectomy patient. Several different surgical techniques and medications were introduced to find the best treatment for it. In this study, we focus more on local analgesia using different method of delivery.

Objective : To compare the effectiveness ofdifferent mode of delivery which is gargle versus throat spray of Benzydamine Hydrochloride in post tonsillectomy pain control

Methodology: This study included 92 patients age from 13 to 40 who underwent tonsillectomy with or without adenotonsillectomy. They were randomly divided into two group with 46 patients in each group labeled as gargle group and spray group. Pain score using Visual Analogue Score (VAS) was assessed for both group at least 6-hour post operation for baseline pain score followed by Day 1, 4 and 7.

Result : In the analysis of between group difference, result for the pain score using VAS showed significant difference between gargle and throat spray) ($p< 0.001$).

Conclusion: Using throat spray as a method to deliver local analgesia give benefit in pain control for post tonsillectomy patients.

CHAPTER 1 : INTRODUCTION

1.1 INTRODUCTION

Tonsillectomy is a common operative procedure done by otorhinolaryngologist. The operation consists of excision or separation of palatine tonsil from its tonsillar fossa with additional removal of adenoid if indicated. Although tonsillectomy is a common procedure, its complications can become significant and unsolved problem to the surgeon.[1] The complications are divided into immediate or delayed. Immediate complications include haemorrhage either primary or reactionary, post tonsillectomy pain, injury to nearest structure and aspiration of blood. Delayed complications include secondary haemorrhage, infection, velopharyngeal insufficiency and poor wound healing. Among them, the most important complications are post tonsillectomy pain and haemorrhage that result in representation of the patient to the emergency department or outpatient clinic after discharge.[2]

Post tonsillectomy pain is believed to occur related to mucosa disruption that cause exposure of the glossopharyngeal nerve endings followed by inflammation and spasms of the pharyngeal muscles that cause ischemia and protracted cycle of pain.[3] Post tonsillectomy pain usually cause bimodal pattern of pain with significant pain lasting till day 7 to 10 post operation.[4,5] For post tonsillectomy operation, the wound healing is by secondary healing which favor more pain and risk for secondary haemorrhage.[6] The wound will produce maximum inflammation between day 3 to 5 post operative period with separation of fibrin clot occurred around day 7 post operation.[7] The pain will impair swallowing process and cause patient refused to eat, delay patient's return to normal diet

and can lead to dehydration and post tonsillectomy haemorrhage.[8] Pain management for post tonsillectomy patient is very important. The principle of post tonsillectomy pain management is to control the pain so that it can encourage patient to eat and assist in healing process and promote early recovery.

Currently, there are many studies conducted to improve pain in post tonsillectomy patient. Several different surgical techniques and medications were introduced to find the best treatment for it. In this study, we focus more on local analgesic by comparing different modes of delivery using the same content of medication which is Benzydamine Hydrochloride (BHCL). BHCL consist of analgesic, anti-inflammatory, anti-pyretic, anti microbial and anti fungal properties.[9] It used is recommended for relief of inflammatory condition of oral cavity, soft tissue and skin[10]. For mouthwash or throat spray in concentration of 0.15% commonly used for relief of inflammatory condition of mouth and throat in case of oral ulcer, mucositis, pharyngitis and laryngitis.[11] Action of BHCL is exclusively based on a patient's perception of pain through local anesthetic properties.[12] It also has anti-TNF alpha effects that may help in the management of mucosal ulcerations.[13,14] Previous studies stated that by 30 seconds gargle or mouth rinse only limited amount of medication was absorbed into buccal tissue evidence by poor systemic availability about 5%.[15,16] From physiology point of view, when there is presence of fluid in the oral cavity, palatopharyngeus and palatoglossus will lower down the soft palate till reached base of tongue as protective mechanism. So that most of the solution will confined in oral cavity and minimal amount will goes to oropharynx area to reach the post operative tonsillar bed. This physiology mechanism also applied during gargle. In some journals that use throat spray method for analgesia such as fusafungine spray and lidocaine spray in post tonsillectomy give significant effective result.[17,18] However, there is no reported study comparing both methods of local anesthesia delivery in post tonsillectomy patient. This

study was conducted to compare the effectiveness of BHCL gargle versus throat spray in pain control post tonsillectomy patient with the assumption by direct spray it will directly deliver the medication into targeted area which cause prolong contact with mucosa. When present of prolong contact with mucosa it will cause more tissue absorption and the effect of medication will become more effective.

CHAPTER 2 : OBJECTIVES OF THE STUDY

2.1 GENERAL OBJECTIVE:

To compare the effectiveness of different modes of delivery of Benzydamine Hydrochloride in post tonsillectomy pain control.

2.2 SPECIFIC OBJECTIVES:

1. To assess pain score in patients using BHCL gargle in post tonsillectomy
2. To assess pain score in patients using BHCL throat spray in post tonsillectomy
3. To compare pain score between patients using BHCL gargle and throat spray in post tonsillectomy

3.1 TITLE PAGE

TITLE : THE EFFECTIVENESS OF BENZYDAMINE HYDROCHLORIDE GARGLE VERSUS THROAT SPRAY IN POST TONSILLECTOMY PATIENT : A RANDOMIZED CONTROLLED TRIAL

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3.2 ABSTRACT

Introduction: Post tonsillectomy pain is an undesirable complication for the patient which can disturb patient emotion and daily activity. There are many studies conducted to improve pain in post tonsillectomy patient. Several different surgical techniques and medications were introduced to find the best treatment for it. In this study, we focus more on local analgesia using different methods of delivery.

Objective : To compare the effectiveness of different mode of delivery gargle versus throat spray of Benzydamine Hydrochloride in post tonsillectomy pain control

Methodology: This study included 92 patients age from 13 to 40 who underwent tonsillectomy with or without adenotonsillectomy. They were randomly divided into two group with 46 patients in each group labeled as gargle group and spray group. Pain score using Visual Analogue Score (VAS) was assessed for both group at least 6-hour post operation for baseline pain score followed by Day 1, 4 and 7.

Result : In the analysis of between group difference, result for the pain score using VAS showed significant difference between gargle and throat spray) ($p< 0.001$).

Conclusion: Using throat spray as a method to deliver local analgesia give benefit in pain control for post tonsillectomy patients.

Keywords : post-tonsillectomy, pain control, gargle, throat spray

3.3 INTRODUCTION

Tonsillectomy is a common procedure done by otorhinolaryngologist. However this operation will result in open wound therefore can cause significant post operative pain. The pain will impair swallowing process and cause patient refused to eat, delay patient's return to normal diet and can lead to dehydration and post tonsillectomy haemorhage.[1] The reported case for morbidity rate cause by post operative pain and secondary bleeding about 1 in 35,000 tonsillectomy cases.[2,3]

Currently, there are many studies conducted to improve pain in post tonsillectomy patient. Several different surgical techniques and medications were introduced to find the best treatment for it. In this study, we focus more on local analgesic by comparing different types mode of delivery using same contents of medication which is Benzydamine Hydrochloride (BHCL).

BHCL consist of analgesic, anti-inflammatory, anti-pyretic, anti microbial and anti fungal properties.[4] For mouthwash or throat spray in concentration of 0.15% commonly used for relief of inflammatory condition of mouth and throat in case of oral ulcer, mucositis, pharyngitis and laryngitis.[5] Action of BHCL is exclusively based on a patient's perception of pain through local anesthetic properties.[3] Previous studies stated that by 30 seconds gargle or mouth rinse only limited amount of medication was absorbed into buccal tissue evidence by poor systemic availability about 5% .[6,7] From physiology point of view, when present of fluid in the oral cavity, palatopharyngeus and palatoglossus will lower down the soft palate till reached base of tongue as protective mechanism. So that most of the solution will confined in oral cavity and minimal amount will goes to oropharynx area. This physiology mechanism also applied during gargle. In some journals that use throat spray method for analgesia such as fusafungine spray and lidocaine spray in post

tonsillectomy give significant effective result.[8,9]

However, there is no reported any study comparing both method of delivery as local anesthesia in post tonsillectomy patient. This study was conducted to compare the effectiveness of BHCL gargle versus throat spray in pain control post tonsillectomy patients with the assumption by direct spray it will directly deliver the medication into targeted area which cause prolong contact with mucosa. When presence of prolong contact with mucosa it will cause more tissue absorption and the effect of medication will become more effective.

3.4 METHODOLOGY

3.4.1 Subjects

This study was carried out at Department of Otorhinolaryngology-Head & Neck Surgery Hospital Ampang and Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian from 1st February 2016 until 31st January 2017. The study was carried out after obtaining approval from Medical Research & Ethics Committee from Hospital Ampang and Human Research Ethics Committee USM (HREC) from Hospital USM and conducted according to the Declaration of Helsinki.

This study is an interventional open-labelled prospective randomized controlled trial. A total of 92 patients who underwent tonsillectomy and fulfilled inclusions and exclusions criteria were recruited from patient attended ORL clinic in both hospitals. They were divided into two groups (group A- gargle, group B- throat spray) using Research Randomizer software. The inclusions criteria are all patients indicated for tonsillectomy/adenotonsillectomy operation with history of recurrent or chronic tonsillitis/adenotonsillitis with age of 13-40 years old. Patient who underwent tonsillectomy/adenotonsillectomy with other procedures in the same setting such as nasal operation or Cautery Assisted Palatal Stiffening Operation (CAPSO), who allergic to Benzydamine Hydrochloride and unable to follow instructions were excluded.

3.4.2 Surgical procedures and intervention

All patients or parents who agree to participate in the study signed the prepared written consent. All selected patients underwent operation done by surgeon who have at least two

years experienced in tonsillectomy operation. This is to avoid pain by unexperienced surgeon which might caused unnecessary injury to nearest structure. Intraoperatively, all patients received the same analgesia (one dose Intravenous Parecoxib Sodium 40 mg and Intravenous Morphine 0.1 mg/kg) given by the anesthetist. Surgeon also used same procedure which was cold dissection technique for all patients involved in this study. This is to standardize method of surgery so that the pain is not influenced by the technique or instrument used.

Post operation patients received the medications as randomized. Patient in the gargle group, used the medication 15 mls each gargle for 30 seconds while for patient in throat spray group, they sprayed the medication directly to tonsillar fossa 2 puffs each side every 3 hourly except during sleep for seven day. If patients from both group still developed pain after using the medications, they will take Cap Celecoxib 200 mg when needed with maximum two times per day as rescue medication. If by using extra analgesia, the pain still not controlled, patient will go to emergency department or contact primary investigator as stated in the information sheet for further treatment. Both group used the medication for one-week duration (7 days post operative).

First pain score was assessed at least 6 hour post operation and when patients were fully conscious from general anesthesia effect before patient started using the medication. First pain score was used as a baseline pain score. Then their pain score were assessed on Day 1, 4 and 7 post operative during follow up using Visual Analogue Score (VAS). We assessed the improvement of pain score between two groups of medications for Day 1, 4 and 7. Beside pain score, patient oral intake, other co-morbid related with post tonsillectomy pain such as bleeding and otalgia and medication's compliance also been assessed.

3.4.3 Statistical analysis

Statistical analysis was done using SPSS for windows 22. Pain score difference between group at several occasion (Day 1, 4 and 7) was evaluated using repeated measure ANOVA test. Repeated measure ANOVA was used because we measured a variable on several occasion for each subject. It also supported by previous study done to compare the effectiveness of two medications used on several occasion.[10]

3.5 RESULTS

A total of 92 patients were recruited in this prospective randomized controlled study and all patients were compliant to the follow up. Thus, all 92 patients were included for further analysis. They were divided into two, whereby 46 patients were in the gargle group and another 46 patients in the throat spray group.

3.5.1Demographics

Out of 92 enrolled patients, 51 (55.4%) patients were female and 41 (44.6%) patients were male. Most of the patients' age range from 13 to 30 years old with mean age 23 years old. Majority of the patients were Malay, which was about 88 (95.7%) followed by Chinese 3 (3.3%) and others 1 (1.1%). For the indications for tonsillectomy, most of the cases is due to recurrent tonsillitis 72 (78.3%), obstructive symptoms including primary snorer and Obstructive Sleep Apnea (OSA) 10 (10.9%) , chronic tonsillitis 7 (7.6%) and others such as recurrent peritonsillar abscess 3 (3.3%). For the tonsil size, 66 (71.7%) patients having tonsil Grade 3 followed by 20 (21.7%) patients with Grade 2 and 6 (6.5%) Grade 4.

Table 1: Demographics and characteristics of both study groups

Demographic characteristics	**BHCL [*n* (%)]**	
	Gargle (*n*=46)	**Throat Spray (*n*=46)**
Age[a]	23 (SD)	22 (SD)
Sex		
Male	23 (25.0%)	18 (20.0%)
Female	23 (25.0%)	28 (30.0%)

Race		
Malay	44(47.8%)	44(47.8%)
Chinese	1(1.1%)	2(2.2%)
Indian	0 (0.0%)	0(0.0%)
Others	1(1.1%)	0(0.0%)
Indications		
Recurrent Tonsillitis	35(38.0%)	37(40.2%)
Chronic Tonsillitis	4(4.3%)	3(3.3%)
Obstructive Symptoms	7(7.6%)	3(3.3%)
Others	0(0.0%)	3(3.3%)
Tonsil Size		
Grade 1	0(0.0%)	0(0.0%)
Grade 2	7(7.6%)	13(14.1%)
Grade 3	36(39.1%)	30(32.6%)
Grade 4	3(3.3%)	3(3.3%)

[a] Mean (SD)

3.5.2 Treatment efficacy

In the analysis of within group difference, for gargle group, it was found that there was no significant difference of pain score between Day 1 and Day 4 post operation (p = 0.06). However, there were significant difference of pain score between Day 1 and Day 7 (p< 0.001) and between Day 4 and Day 7 (p< 0.001).

However for throat spray group, significant different of pain score were found for all comparisons (Day 1 and Day 4, Day 1 and Day 7, Day 4 and Day 7) (Table 2). In the analysis of between group difference, result for the pain score using VAS showed significant

difference between gargle and throat spray ($p< 0.001$) (Table 3). Comparison between different time group (Day 1, Day 4, Day 7) for pain score were statistically significant for Day 4 and Day 7 but not for Day 1 (Table 4). The mean pain score lower in spray group compare to gargle and the mean difference higher during Day 4. So that we can conclude that the pain score were better in spray group compare to the gargle group.

Table 2: Comparison of pain score (VAS) within each BHCL group with time

Comparison	**BHCL Gargle**		**BHCL Throat Spray**	
	Mean difference (95% CI)	***p*-value**	**Mean difference (95% CI)**	***p*-value**
Day 1 – Day 4	0.48 (-0.02, 0.97)	0.060	1.37 (0.91, 1.82)	< 0.001
Day 1 – Day 7	2.04 (1.49,2.60)	<0.001	2.67 (2.19,3.16)	<0.001
Day 4 – Day 7	1.57 (1.10,2.03)	<0.001	1.30 (0.90,1.71)	<0.001

Repeated measure ANOVA within group analysis was applied followed by pairwise comparison with 95% confidence interval adjustment by Bonferroni correction.

Table 3: Overall mean differences of pain score between gargle and spray methods.

BHCL group	Mean (95% CI)	Mean difference (95% CI)	F-stats (df)[a]	*p*-value
Gargle	4.18 (3.80, 4.56)	0.96 (0.43, 1.50)	12.65 (1)	< 0.001
Spray	3.22 (2.84, 3.60)			

[a]Post-hoc test not applicable for two treatment groups

Table 4: Comparison of pain score among two different treatment groups based on time

Time	BHCL group	Mean Pain Score	Mean difference (95% CI)	*p*-value
Day 1	Gargle	5.02	0.46 (-0.14, 1.05)	0.132
	Spray	4.57		
Day 4	Gargle	4.54	1.35 (0.67, 2.03)	< 0.001
	Spray	3.20		
Day 7	Gargle	2.98	1.09 (0.50, 1.68)	< 0.001
	Spray	1.89		

Repeated measures ANOVA between group analysis with regard to time was applied. Assumption of normality, homogeneity of variances and compound symmetry were checked and were fulfilled.

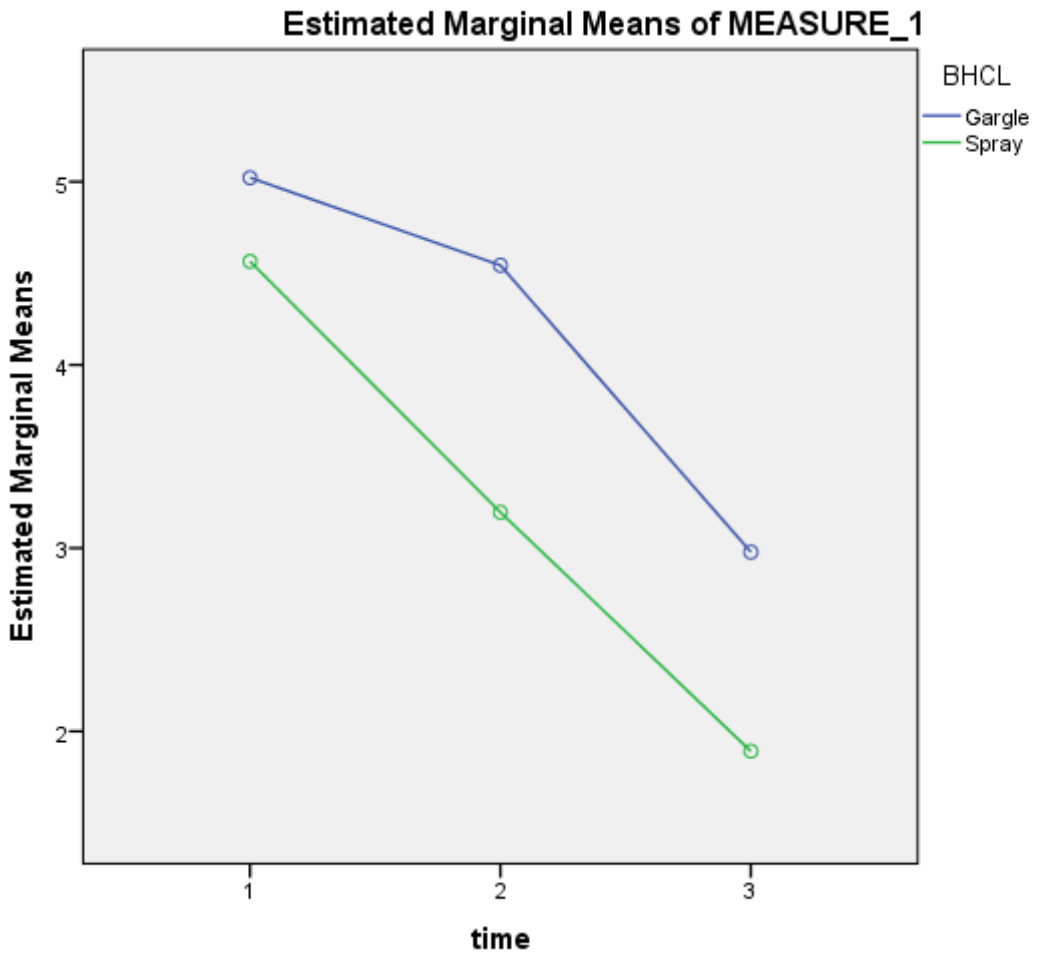

Fig 1. Pain score (VAS) between BHCL gargle group and BHCL throat spray.1-Day 1 post opeartion, 2- Day 4 post operation, 3-Day 7 post operation.

Throughout the study, three (3.2%) from total patient developed bleeding which all in the gargle group. One of the bleeding cases occur day 1 after surgery which most probably due to surgical technique and required examination under general anaesthesia to stop the bleeding. Another two patients, the bleeding occurred at Day 4 post operation and required re-hospitalization and both patients were treated conservatively. About 40 (43.5%) having otalgia which came from both groups and more common at Day 1 and Day 4 post operation. For gargle group, 17 (18.5%) occur at Day 1, 9 (9.8%) at Day 4 and 4 (4.3%) at Day 7. For spray group, 6 (6.5%) occur at Day 1, 3 (3.2%) occur at Day 4 and 1(1.1%) Day 7. For

rescue analgesia, about 32 (34.8%) patients need to take extra analgesia due to uncontrolled pain. In gargle group, 11 (12.0%) patients need extra analgesia at Day 1, 7 (7.6%) at Day 4 and 5 (5.4%) at day 7. While in spray group, 4 (4.3%) patients required extra analgesia at Day 1, 3(3.3%) Day 4 and 2 (2.2%) at Day 7. For oral intake, majority of patient in both groups having moderate to good intake at Day 4 and 7.

3.6 DISCUSSION

This study is designed to compare the effectiveness of two methods of BHCL application for post tonsillectomy pain control. In this study we have demonstrated that BHCL throat spray is superior to BHCL gargle in reducing post tonsillectomy pain and it is statistically significant different between both method. To our knowledge, this is the first study conducted to compare different method of delivery local analgesia using BHCL in post tonsillectomy pain control.

Local analgesia was used in this study as it plays a major role to control post tonsillectomy pain. Some authors suggested that post tonsillectomy pain developed due to inflammation process, irritation of nerve ending and cyclical spasm of the exposed pharyngeal muscles.[11] For local anesthesia, there were many studies conducted either using pharmacology or non pharmacology technique which were applied before, during or after tonsillectomy operation. Ozlugedik S et al compared oral honey applications with placebo which give significant result in VAS pain score within first two post operative day.[12] Kim et al conducted a study regarding efficacy of TachoComb® (A fibrinogen/thrombin-based collagen fleece) also showed significant result in reducing pain and risk of bleeding.[13] Baradaranfar et al done on study using clindamycin with assumption of using antibiotic will reduce bacteria colonization and cause less pain.[10] However, this study did not show significant result.

Systemic analgesia also gives effective result in reducing pain, however study showed that they have association with other side effects. For NSAIDs group (eg: Salicylate, Endomethacin) it associated with increased incidence of haemorrhage due to their effect as an inhibitor for prostaglandin and platelet[14] while opioids group which widely used have

their known side effects such as vomiting, over sedation and risk of respiratory depression. In this study no patient has been reported to have any medication adverse effect either from gargle or throat spray group. BHCL has alkaline pH which becomes more concentrated in inflamed tissue but not in normal tissue that can reduce systemic absorption[15], and reduced risk of systemic adverse reaction.

From this study it also supports our hypothesis by using throat spray that the medication will directly reach the operation site compare to gargle. In addition, for throat spray, time contact between medications with targeted area also more prolonged compare to gargle. As per gargle, physiologically with the presence of fluid in the oral cavity, the palatoglossal and palatopharyngeus muscles come in contact with the base of tongue as protective mechanism to protect aspiration. As a result, the solution mainly confined in the oral cavity and minimal amount only reached the tonsillar fossa or operation site. However, there are no proper tools yet to objectively measure how far the medication solution can reach the oropharynx region by gargle and no previous study performed to compare our study result.

Desiderio Passali et al, done a study to compare the effectiveness of Ketoprofen Lysin Salt mouthwash versus BCHL mouthwash in acute pharyngeal inflammation. From this study, only 25% of BHCL and 32% of KLS experienced improvement in pain more than 50% after 6 hours using the medication.[16] It showed that both mouthwash used as a gargle give minimal effect in pain control. However in study done by Akbas et al using fusafungine throat spray showed significant pain improvement in post tonsillectomy patient after Day 7 to Day 14 post operation.[8] Another study done by Kaygusuz use lidocaine spray give significant result compare to placebo for pain score on Day 1 and Day 3.[9] In this study they used 4 mg/kg of 10% lidocaine HCl was sprayed onto the tonsillectomy fossa four times a day compare with placebo using 9% NaCl. From the above study it showed that throat spray

give positive result compare to the gargle. However there are no reported study comparing both methods of delivery using same medications.

BHCL has been chosen in this study due to it availability in both gargle and throat spray preparation.It also has anti-inflammatory, analgesic and antimicrobial properties which can help in reducing pain and promote healing and recovery process. It also has anti-TNF alpha effects that may help in the management of mucosal ulcerations.[17,18] It used is recommended for relief of inflammatory process occur over the oral cavity, soft tissue and skin.[19] Action of BHCL is mainly via patient's perception of pain through local anesthetic properties.[16]

In this study, we try to avoid other factors that can influence post tonsillectomy pain such as surgeon factors, instruments factors and anaesthetic drugs by standardizing it in the protocol. For the surgeon we make sure all the surgeons have at least 2 years of experience in doing the operation. We unable to limit to a single surgeon performing the procedure as this study were done at two centres and involved a university hospital. The instrument used during the procedure was also standardized to cold instrument only as it is mostly used instruments in both centers . Some newer surgical instruments such as Harmonic Scalpel and Coblator which theoretically operated in lower temperature cause less thermal tissue injury and less pain. Parson at el reported from their study comparing coblator, harmonic and electrocautery showed that using coblator result in decreasing post-operative pain compare to harmonic and electrocautery.[20]

In this study, we assessed the pain score by directly ask the patient using Visual Analogue Score (VAS) as all our patients aged thirteen and above who able to give their own pain score. We did not include children less than 12 years old as most of the children need help from parents to give score and usually it is difficult to be assessed. However, although the VAS is a good scale and are widely used and all our subjects give their own

pain score, the accuracy of the pain score is still questionable as pain itself is a subjective measurement. The pain threshold also depends on the personal and private experience of each patient. Thus, we also need to evaluate other elements that may be associated with poor control of pain such as development of other morbidity (otalgia and bleeding), extra analgesia consumption and oral intake. Otalgia may have strong association with poor pain control in view of referred pain from same nerve supply. In this study we do assess development of otalgia post-operatively, however no further analysis was done to look for relation between pain score and otalgia.

Throughout the study, no major complications from medications was reported except several patient claimed having stinging sensation during spray or gargle. However patient still able to tolerate it and continue the medication. There were also some minor complications from surgery such as injury to the lips and tongue due to instruments handling which not interfere with the patient pain.

3.7 CONCLUSION

Throat spray is a more effective method to deliver local analgesia in post tonsillectomy patient due to direct application of medication into the tonsillar fossa compared to the gargle.

3.8 LIMITATION

One of the limitation in this study is a pain score itself is a subjective measurement depend on individual perception. Beside that technique of using medication also can influence the result although we already taught the patients and care taker regarding proper technique. In this study we also unable to fix one surgeon for operation and there are no proper tools to measure how far the medication can reach the oropharynx by gargle method.

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